The committees will discuss the supplemental new drug application (sNDA) 204275-S001, for fluticasone furoate and vilanterol inhalation powder (tradename Breo Ellipta) submitted by GlaxoSmithKline for the once daily maintenance treatment of asthma in patients 12 years of age and older. The discussion will include efficacy data, but the focus of the meeting will be safety, including the adequacy of the safety database to support approval and whether a large safety trial to evaluate serious asthma outcomes is recommended.

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter/Officer</th>
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<tr>
<td>8:00 a.m.</td>
<td>Call to Order and Introduction of Committee</td>
<td>Erik Swenson, MD&lt;br&gt;Acting Chairperson, PADAC</td>
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<td>8:05 a.m.</td>
<td>Conflict of Interest Statement</td>
<td>Cindy Hong, PharmD&lt;br&gt;Designated Federal Officer, PADAC</td>
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<td>8:15 a.m.</td>
<td>FDA Opening Remarks</td>
<td>Sally Seymour, MD&lt;br&gt;Deputy Director for Safety&lt;br&gt;Division of Pulmonary, Allergy, Rheumatology Products (DPARP)&lt;br&gt;Office of Drug Evaluation (ODE) II&lt;br&gt;Office of New Drugs (OND), CDER, FDA</td>
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<td>8:30 a.m.</td>
<td>APPLICANT PRESENTATIONS</td>
<td>GlaxoSmithKline</td>
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<td>BREO ELLIPTA 100/25 and 200/25 (Fluticasone furoate / Vilanterol) Introduction</td>
<td>Katharine Knobil, MD&lt;br&gt;Senior Vice President&lt;br&gt;Research and Development&lt;br&gt;GlaxoSmithKline</td>
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<td></td>
<td>BREO ELLIPTA 100/25 and 200/25 (Fluticasone furoate / Vilanterol) Asthma: Efficacy and Safety</td>
<td>Courtney Crim, MD&lt;br&gt;Director, Project Physician Lead&lt;br&gt;GlaxoSmithKline</td>
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<td>Clinical Perspectives on Asthma Management</td>
<td>Eugene Bleecker, MD&lt;br&gt;Director&lt;br&gt;Center for Genomics and Personalized Medicine Research&lt;br&gt;Professor of Medicine&lt;br&gt;Wake Forest Baptist Health</td>
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<td>10:00 a.m.</td>
<td>Clarifying Questions to the Presenters</td>
<td>Katharine Knobil, MD</td>
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10:20 a.m.  BREAK

10:35 a.m.  FDA PRESENTATIONS

Utilization Patterns of Breo Ellipta and Long-Acting Beta2-Adrenergic Agonists (LABAs)

Tracy Pham, PharmD
Drug Utilization Analyst
Division of Epidemiology II
Office of Surveillance and Epidemiology
CDER, FDA

Clinical Review of Efficacy
Banu Karimi-Shah, MD
Clinical Team Leader
DPARP, ODE II, OND, CDER, FDA

Meta-analysis of Asthma Related Serious Adverse Events
Janelle K. Charles, PhD
Mathematical Statistician
Division of Biometrics VII
Office of Biostatistics
Office of Translational Sciences, CDER, FDA

Efficacy in Subgroups and Risk-Benefit Considerations
Banu Karimi-Shah, MD

Pediatric Perspective on the Efficacy and Safety of Breo Ellipta in Patients 12 to 17 Years of Age
Ann McMahon, MD, MS
Deputy Director of Science
Office of Pediatric Therapeutics
Office of the Commissioner, FDA

11:45 a.m.  Clarifying Questions to the Presenters

12:00 p.m.  LUNCH

1:00 p.m.  Open Public Hearing

2:00 p.m.  Charge to the Committee
Sally Seymour, MD

2:05 p.m.  Questions to the Committee/Committee Discussion

3:00 p.m.  BREAK

3:15 p.m.  Questions to the Committee/Committee Discussion (cont.)

5:00 p.m.  ADJOURNMENT